DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 17, 2014

Anthogyr SAS
Ms. Thérése Candau
Regulatory Affairs Engineer
2237 Avenue Andre Lasquin
Sallanches, France 74700

Re: K141450
Trade/Device Name: Axiom® 2.8
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: August 26, 2014
Received: September 3, 2014

Dear Ms. Candau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address: http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: AXIOM® 2.8

Indications for Use:

ANTHOGYR implants are intended for use as artificial root structures for replacement of missing teeth. They can be used for fixation of single tooth restorations.
ANTHOGYR dental systems are indicated for one-stage or two-stage surgery. It is up to the practitioner to decide whether immediate or delayed loading is most appropriate, based on clinical factors like good primary stability and appropriate occlusal loading.
Axiom® 2.8 implants are indicated for single replacement of mandibular incisors and lateral maxillary incisors in cases presenting a restricted mesiodistal space.
The prosthetic components of the Axiom 2.8 product line are intended to ensure support for single crowns only.

Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

SECTION 5
510(K) SUMMARY

510(k) SUMMARY

Submitter	**ANTHOGYR SAS** 2237, avenue Andre Lasquin SALLANCHES, FRANCE 74700 Registration Number: 8020776
Contacts	Ms. Thérèse CANDAU m.candau@anthogyr.com Phone: (33) (0)4 50 58 02 37 Fax (33) (0)4 50 93 78 60 Regulatory: Dr. Isabelle DRUBAIX (PhD) IDEE CONSULTING idrubaix@nordnet.fr
Trade Name	AXIOM® 2.8
Classification Name	ENDOSSEOUS DENTAL IMPLANT
Class	II
Product Code	DZE / NHA
CFR section	21CFR 872.3640
Device panel	DENTAL
Legally marketed predicate devices	Axiom® REG (K101913/K131066) manufactured by Anthogyr NobelActive 3.0 (K102436) manufactured by Nobel Biocare 3.0 mm Integra CP Implant (K101849) manufactured by Bicon Sendax MDI and MDI PLUS (K031106) manufactured by Imtec
Description	The AXIOM® 2.8 implant system has been designed in order to enhance the functional and aesthetic integration of implant supported restorations. The implant-abutment combination can support occlusal charge without risk of damaging the restoration and will not generate hazardous peek of stress at the prosthetic interface level. The file concerns the implants and abutments. Implants: Replacement of a missing root for placement of a dental restoration. Material: Ti6Al4V Surface treatment: BCP® Dimensions: Ø2.8, length: 10-14 mm Abutments: Provide support for a single permanent restoration. Material: Ti6Al4V Dimensions: Ø2.8 Angle: 0-23° Gingival height: 1-5.5 mm

	Temporary abutments: Provide support for a temporary restoration. Material: PEEK Dimensions:Ø2.8 Gingival height: 1-5.5 mm
Indications for use	ANTHOGYR Axiom® implants are intended for use as artificial root structures for replacement of missing teeth. They can be used for fixation of single tooth restorations. ANTHOGYR dental systems are indicated for one-stage or two-stage surgery. It is up to the practitioner to decide whether immediate or delayed loading is most appropriate, based on clinical factors like good primary stability and appropriate occlusal loading. Axiom® 2.8 implants are indicated for single replacement of mandibular incisors and lateral maxillary incisors in cases presenting a restricted mesiodistal space. The prosthetic components of the Axiom 2.8 product line are intended to ensure support for single crowns only.
Performance data	ANTHOGYR AXIOM® 2.8 conforms to Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments - Guidance for Industry and FDA Staff Document issued on May 12, 2004. A fatigue testing according to the standard ISO 14801 (2007) has been performed. Results demonstrate comparable mechanical properties to the predicate device. No clinical data has been presented.
Substantial equivalence	ANTHOGYR AXIOM® 2.8 is substantially equivalent to its predicate devices in terms of intended use, material, design, mechanical properties and function. Non clinical performance testing according to special control demonstrate that ANTHOGYR Endosseous dental implant system AXIOM® 2.8 is as safe, as effective, and performs as safely and effectively as its predicate devices.
Preparation date	August 8th, 2014